



Patent Docket P1989R1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Charles P. Semba Serial No.: 10/697,142 Filed: 30 October 2003 For: PLASMINOGEN ACTIVATOR VARIANT FORMULATIONS	Group Art Unit: Unassigned Examiner: Unassigned Confirmation No: Unassigned CUSTOMER NO: 09157  <b>CERTIFICATE OF MAILING</b> I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on February 9, 2004 <i>T.E. Marrs</i> Tom Marrs
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**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR § 1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

☒ **37 CFR § 1.97(b)**

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR § 1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR § 1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR § 1.114.

☐ **37 CFR § 1.97(c)**

- by the applicant after the period specified in 37 CFR § 1.97(b), but prior to the mailing date of any of a final action under 37 CFR § 1.113, or a notice of

allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) **or** a statement as specified in 37 CFR §1.97(e), as checked below.

☐ **37 CFR §1.97(d)**

- after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) **and** a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

**A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified).**

**A copy of the items on PTO-1449 is supplied herewith. U.S. Patents are not included.**

Those patent(s) or publication(s) which are marked with an asterisk (\*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial No. , filed and relied upon in this application for an earlier filing date under 35 USC §120.

A concise explanation of relevance of the items listed on PTO-1449 is:

☒ not given

☐ given for each listed item

☐ given for only non-English language listed item(s) [Required]

☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR § 1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR § 1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630.

Respectfully submitted,

GENENTECH, INC.

Date: February 8, 2004

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Patent and Trademark Office

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Serial No.

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## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Semba Charles P.

Filing Date

30 Oct 2003

Group

Not Assigned

## U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	1	2001/0021811A1	13.09.01	Yock			
	2	5,612,029	18.03.97	Bennett et al.			
	3	5,849,736	15.12.98	Wityak et al.			
	4	5,865,178	02.02.99	Yock			
	5	6,346,517	12.02.02	Wong et al			

## FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes No
	6	WO 00/53264	14.09.00	PCT			
	7	WO 95/14683	01.06.95	PCT			
	8	WO 98/028326	02.07.98	PCT			

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

9	Allie et al., "Novel Combination Thrombolytic Therapy in Limb Salvage: Mechanical Thrombectomy (Rheolytic Thrombectomy with Angiojet) and Chemical Thrombolysis (Tenecteplase) "Power-Pulse Spray" Technique" <u>Am. J. Cardiol.</u> 90:108H (2002)
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11	Arepally et al., "Weight-based rt-PA Thrombolysis Protocol for Acute Native Arterial and Bypass Graft Occlusions" <u>J. Vasc. Interv. Radiol.</u> 13:45-50 (2002)
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19	Calis et al., "Bioactivity of cryopreserved alteplase solutions" <u>Am. J. Health Syst. Pharm.</u> 56:2056-2057 (1999)
20	Castaneda et al., "Catheter-directed Thrombolysis in Deep Venous Thrombosis with Use of Reteplase: Immediate Results and Complications from a Pilot Study" <u>J. Vasc. Interv. Radiol.</u> 13:577-580 (2002)
21	"Cathflo Activase. Full Prescribing information" 2002 Physicians Desk Reference, Montvale, NJ:Thomas Medical Economics Co. (2002)

Examiner	Date Considered
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## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

22	Chang et al., "Daily Catheter-directed Single Dosing of t-PA in Treatment of Acute Deep Venous Thrombosis of the Lower Extremity" <u>J. Vasc. Interv. Radiol.</u> 12:247-252 (2001)
23	Collen, D. et al., "Comparative thrombolytic properties of tissue-type plasminogen activator and of a plasminogen activator inhibitor-1-resistant glycosylation variant, in a combined arterial and venous thrombosis model in the dog" <u>Thrombosis and Haemostasis</u> 72(1):98-104 (1994)
24	Cornelius et al., "Adsorption of proteins from infant and adult plasma to biomaterial surfaces" <u>J. Biomed. Mater. Res.</u> 15:622-632 (2000)
25	Davidian et al., "Initial Results of Reteplase in the Treatment of Acute Lower Extremity Arterial Occlusions" <u>J. Vasc. Interv. Radiol.</u> 11:289-294 (2000)
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31	Graul et al. <u>Xemilifiban; Drugs of the future</u> 22:508-517 (1997)
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33	Hofmann et al., "GPIIb-IIIa Receptor Inhibitors: What the Interventional Radiologist Needs to Know" <u>Cardiovasc. Interv. Radiol.</u> 24:361-367 (2001)
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36	Keyt et al., "A Faster-Acting and More Potent Form of Tissue Plasminogen Activator." <u>Proc. Natl. Acad. Sci. USA</u> 91:3670-3674 (1994)
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40	Mewissen et al., "Catheter-directed Thrombolysis for Lower Extremity Deep Venous Thrombosis: Report of a National Multicenter Registry" <u>Radiology</u> 211:39-49 (1999)
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42	Ouriel et al., "A Comparison of Recombinant Urokinase with Vascular Surgery as Initial Treatment for Acute Arterial Occlusion of the Legs" <u>New England J. of Medicine</u> 16:1105-1111 (1998)
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46	Razavi et al., "Initial Clinical Results of Tenecteplase (TNK) in Catheter-Directed Thrombolytic Therapy" <u>J. Endovasc. Ther.</u> 9:593-598 (2002)
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53	Semba et al., "Alteplase and Tenecteplase: Applications in the Peripheral Circulation" <u>Tech. Vasc. Interv. Radiol.</u> 4:99-106 (2001)
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55	Semba et al., "Alteplase Stability and Bioactivity after Thrombolysis-Facilitated Rheolytic or High-Speed Maceration Thrombectomy" <u>J. Vasc. Interv. Radiol.</u> 13 2 (Part 2):S76 (Feb 2002)
56	Semba et al., "Tenecteplase (TNK): Protein Stability and Bioactivity of Thawed or Diluted Solutions Used in Peripheral Thrombolysis" <u>J. Vasc. Interv. Radiol.</u> 13(2):Part 2: S75 (Feb 2002)
57	Semba et al., "Tenecteplase: Stability and Bioactivity of Thawed or Diluted Solutions Used in Peripheral Thrombolysis" <u>J. Vasc. Interv. Radiol.</u> 14:475-479 (2003)
58	Semba et al., "Thrombolytic Therapy with Use of Alteplase (rt-PA) in Peripheral Arterial Occlusive Disease: Review of the Clinical Literature" <u>J. Vasc. Interv. Radiol.</u> 11:149-161 (2000)
59	Shortell et al., "Safety and efficacy of limited-dose tissue plasminogen activator in acute vascular occlusion" <u>J. Vasc. Surg.</u> 34:854-859 (2001)
60	The STILE Investigators, "Results of a Prospective Randomized Trial Evaluating Surgery Versus Thrombolysis for Ischemia of the Lower Extremity. The STILE trial" <u>Ann. Surg.</u> 220:251-268 (1994)
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Yamazaki et al., "Effects of DX-9065a, an Orally Active, Newly Synthesized and Specific Inhibitor of Factor Xa, against Experimental Disseminated Intravascular Coagulation in Rats" Thromb. Haemost. 72:393-396 (1994)

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USCOMM-DC 80-398.